

Atty. Docket No.: 364106/0176
SBP:JFD



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: George S. Gabriel et al.

Serial No.: 09/173,134

Art Unit: 3643

Filed: October 15, 1998

Examiner: Son T. Nguyen

For: MULTISPECIES RODENT CAGE

DECLARATION OF NEIL CAMPBELL

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Declaration is submitted by the undersigned, Neil Campbell, who makes the following Declaration:

1. I am currently President of Lab Products, Inc. ("LPI"), Assignee of Record of U.S. Patent Application Serial No. 09/173,134 (the "Application"). I have been involved continuously in the development, marketing and sales of laboratory animal cages and systems for LPI for over 30 years.

2. I am a co-inventor of the inventions described and claimed in the Application. As such, I have read and understand the Application and the amendments thereto, and I am familiar with the claims of the Application as they presently stand.

3. The discovery of the problem to which the invention claimed in this Application is directed was a significant aspect of the invention, and demonstrates why the instant invention is patentable over the prior art.

4. As background, the Institute for Laboratory Animal Research (ILAR) publishes guidelines for cage size, each set of guidelines corresponding to a different animal size and/or species. These guidelines are meant to provide information so that different species of animals may be properly housed during laboratory experiments. For example, for mice that weigh more than 25 grams, a cage having a floor dimension of at least 15 square inches per mouse is required. Similarly, rats up to 400 grams in size require a cage floor dimension of at least 40 square inches per rat. For hamsters that weigh more than 100 grams, a cage floor dimension of at least 19 square inches per hamster is required.

5. Prior to the present invention, research laboratories performing animal studies typically had many types of rack and cage systems, each type being designed to house a specific animal species while meeting ILAR guidelines for that specific species, and consequently, each cage and rack type had its own particular size and dimensions.

6. As further background, the following information regarding the development and use of animal rack and cage systems is provided. In the late 1940's, the performing of toxicology and other scientific experiments on animals became more prevalent. During this period, animals were typically housed in a variety of containers, including glass jars, boxes, and stainless steel containers wherein the animal would be located on a wire grid "floor," with a metal tray positioned below to collect fecal matter from the animal. These animal containers typically were designed in an ad-hoc fashion, on a study-by-study as-needed basis. As such,

these animal containers were not formed in any standard size or shape, were relatively expensive to fabricate, and were generally produced in low volumes.

7. During the early 1950's, as the use of plastics in manufacturing became more common, work began on the development of plastic animal cages. Plastic animal cages were generally less expensive to make than previously produced metal and glass cages, and were easier to clean and store (some allowing for nesting of containers) than the previously designed metal and glass animal cages.

8. By the early 1960's, different sizes of plastic animal cages began to arise. Generally, plastic cages thought to be acceptable for housing mice were developed. Then, when cages were needed to house, for example, rats, larger or taller cages were provided because the rats were generally larger and taller than mice. Again, typically, each scientist performing an experiment would tend to design an animal cage and rack system in accordance with the specific arbitrary requirements of the particular experiment or study to be performed.

9. By the 1960's, the ILAR guidelines had been established. These guidelines have been updated and revised over the years. The ILAR guidelines are not a law, but instead, are use and care guidelines for the manner in which laboratory animals should be housed. While not legal standards, the ILAR guidelines are used for accreditation purposes by, for example, the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC). AAALAC international accreditation is crucial for research laboratories, because such accreditation is often necessary for the labs to obtain funding, to attract top researchers, and to maintain a solid reputation in the animal research field.

10. During the late 1970's, and early 1980's, as research laboratory space was becoming more and more expensive, it became more important to be able to house relatively large lab animal populations in relatively smaller spaces. In other words, increased animal storage density became more important.

11. As animal density became more important, manufacturers began to develop standardized cage and rack systems for different species types. For example, one type was manufactured to meet the ILAR guidelines for mice, while another system was designed and manufactured to meet the ILAR guidelines for rats. Accordingly, each generation of cage and rack system for mice was made more efficient, as was each generation of rack and cage system designed to house rats.

12. For example, U.S. Patent No. 4,989,545 to Sheaffer et al. ("Sheaffer"), describes a ventilated cage and open rack system in which the rack includes a filter bonnet for removing air from a filter bonnet positioned on top of the sidewalls of the cage. Sheaffer is assigned to LPI, which, as stated above, is the assignee of record of the present Application. Because LPI manufactured the cages depicted in the Sheaffer patent, I have personal knowledge that the animal cage and rack systems described in then Sheaffer patent were each directed to a single animal type or size. There is not a single word in the Sheaffer patent that would suggest a cage wherein the overall dimensions of the cage are designed to simultaneously meet ILAR guidelines for more than one animal species.

13. U.S. Patent No. 5,894,816 to Coiro, Sr. et al. ("Coiro") is directed to an animal cage wherein the dimensions of the floor of the cage are larger than a standard cage having the same top dimensions, so that a larger floor space may be obtained with a cage that still fits a

Best Available Copy

previously designed lid. Again, I am aware of products sold related to Coiro, and each of these is designed to be used with a single species or size of animal. Coiro does not discuss a cage wherein the overall dimensions of the cage are designed to simultaneously meet ILAR guidelines for more than one animal species.

14. As another example, prior to the time of the conception of the present invention, LPI was selling numerous other cage level barrier rodent cages and systems under the brand names MOUSE MICRO ISOLATOR SYSTEM, LOW PROFILE MOUSE MICRO ISOLATOR SYSTEM, RAT MICRO ISOLATOR SYSTEM, LARGE MOUSE MICRO ISOLATOR SYSTEM, HAMSTER MICRO ISOLATOR SYSTEM, GUINEA PIG MICRO ISOLATOR SYSTEM, SUPER MOUSE MICRO ISOLATOR SYSTEM, and SUPER MOUSE 750 MICRO ISOLATOR SYSTEM. Each of these various cage level barrier rodent cages and systems are intended for use with a single, specific rodent type, and each is sized to house a single specific rodent type or a plurality of that specific rodent type, and to meet ILAR standards for the specific rodent type.

15. As stated above, prior to the conception of the instant invention, each cage and rack system sold in the market was designed and dimensioned specifically to meet ILAR guidelines for a specific animal species. Because each cage and rack system, for reasons stated above, was built around the size of the cage, each of the different rodent cages and systems had different cage and rack footprints for different rodent types. Thus, a mice-only cage and system takes up a different amount of laboratory and inventory space than a rat-only cage and rack system. Consequently, efficient use of valuable laboratory and inventory space was ignored

because the type of rodent being evaluated (and thus the size of the cage and system required) would be subject to change, based on the type of rodent that would be used by a particular study.

16. Prior to the invention claimed in the Application, there was no recognition that the inefficient use of lab space was caused by the size of animal cages. The inventory and size problems experienced in the industry were a consequence of the size and the complexity of each of the different rack and cage systems sold by each manufacturer. Accordingly, efforts to solve these problems were directed at producing smaller profile racks and cages of simpler design, each for a single particular species.

17. My co-inventors and I discovered that the fact that each particular cage and rack system for a specific animal species had a unique footprint was in fact a problem. Prior to this time, no one in the industry recognized the fact that each of the then current systems were only designed to efficiently house a single species of animal within ILAR guidelines was a problem.

18. Our conception recognized that there was a problem and that the solution to the problem was to provide a cage and rack system that was capable of efficiently housing more than one species of animal, while simultaneously meeting the ILAR requirements for housing each of those animal species. In other words, the invention begins with the recognition of the problem, which is to invent a cage and rack system with respect to the overall efficiency of housing multiple species, instead of just housing one specific species.

19. By simultaneously looking at the combined efficiency of housing multiple species of animals, my co-inventors and I were able to design a cage and rack system that solved the inventory and planning problems discussed above.

Best Available Copy

20. The inventors of the instant invention also recognized that the overall dimensions of the cage must be designed to simultaneously meet ILAR guidelines for more than one animal species.

21. Similarly, the inventors of the instant invention recognized that there is a need of laboratories to move the rack and cage systems from room to room, and have a rack and cage system that can easily pass through a standard doorway (having a height of 6'8" and a width of 36"), while simultaneously meeting the ILAR guidelines.

22. The result of this inventive idea is embodied in a cage having a floor with a footprint of 80 square inches and a rack with a depth that is less than or equal to 36 inches, and that could house any of a plurality of rodent types (e.g., rats, mice, hamsters and guinea pigs).

23. This embodiment of the invention is claimed, for example, by claim 1 of the Application, which is directed to a multipurpose cage level barrier rodent cage for housing multiple species of rodents, including a plurality of mice or rats in a ventilated rack and cage system, the cage comprising a cage bottom having a plurality of integral side walls, a floor and an open top end, the floor having a length l and a width w wherein $80 \text{ square inches} \leq l \times w \leq 110 \text{ square inches}$.

24. This embodiment of the invention is also claimed, for example, by claim 3 of the Application, which recites a cage level barrier cage ventilated rack and cage system for housing a plurality of types of rodents including a plurality of mice or rats within a cage, the system comprising a double sided rack, the rack having a depth; at least one cage disposed in the rack, the cage having a cage bottom, the cage bottom having a plurality of integral side walls, a floor and an open top, and the length of the cage being less than substantially a 18 inches.

Best Available Copy

25. Claim 8 of the Application is also directed to the invention, claim 8 being directed to a cage level barrier cage ventilated rack and cage system for housing a plurality of types of rodents including a plurality of mice or rats within a cage, the system comprising: a double sided rack, the rack having a depth; and a cage disposed in the rack, the cage having a cage bottom, the cage bottom having a plurality of integral side walls, a floor and an open top, and the length of the cage being less than substantially a 18 inches; wherein the cage bottom has a length l and a width w , and wherein $80 \text{ square inches} \leq l \times w \leq 110 \text{ square inches}$.

26. Likewise, this embodiment of the invention is claimed by claim 9 of the Application, which is directed to a cage level barrier cage ventilated rack and cage system for housing a plurality of types of rodents including a plurality of mice or rats within a cage, the system comprising: a double sided rack, the rack having a depth; and a cage disposed in the rack, the cage having a cage bottom, the cage bottom having a plurality of integral side walls, a floor and an open top, and the length of the cage being less than substantially a 18 inches; wherein the rack has a depth and the cage rests within said rack so that the length of the cage at least partially overlaps the depth of the rack and a portion of the cage extends beyond the rack, the portion having a length and the sum of the length of the portion and the depth of the rack is less than or equal to substantially 36 inches.

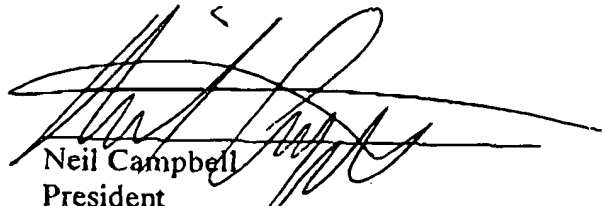
27. Accordingly, my co-inventors and I discovered that a problem existed, and it is apparent that the discovery of that problem was an inventive aspect of the invention claimed in the Application. It is significant that the cited prior art, particularly the Sheaffer and Coiro

Best Available Copy

patents never discuss this problem and provide no direction to the inventors' solution that is described and claimed in this application.

28. I hereby declare that all statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Dated: JUNE 26, 2003


Neil Campbell
President
Lab Products, Inc.